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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,491	01/11/2002	Chaim Sukenik	LUZZATTO 3.0-095	6432

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EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/043,491

Applicant(s)

SUKENIK ET AL. *gn*

Examiner

Nikita R Veniaminov

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 17-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7,9-13 and 16 is/are rejected.
- 7) ☒ Claim(s) 3, 6, 8, 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, 4, 5, 7, 9-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Sorensen et al. (US 6,500,108 B1). Sorensen et al. ('108) teach a device or temporary, or permanent therapeutic implant, or stent for use in angioplasty comprising a surface layer that has incorporated therein at least one radioactive nuclide (see Figure 2(18) and column 5, lines 19-21); a substrate and a self assembled layer that has incorporated therein at least one radioactive nuclide, and having no other protective layers or coating over said self-assembled layer (see Figure 2(16 and 18) and column 5, lines 19-21); wherein the self-assembled layer is an anchored SAM (see column 5, lines 16-30); wherein the anchored SAM is selected from the group consisting of monolayers anchored by thiol or amine (see column 6, lines 8-41); the device comprising a chemically functionalized SAM incorporating at least one radioactive nuclide such as I-131 (see column 16, lines 26-33) attached at the surface of the device (see column 9, lines 38-48).

Response to Arguments

3. Applicant's arguments filed on July 28, 2003 have been fully considered but they are not persuasive. Applicant argues that "the key difference is that in Sorensen an intermediary layer is necessary between the substrate and the self-assembling surface layer"; and "Sorensen requires a layer of gold between the self assembling surface layer and the substrate". Examiner states that the device of Sorensen et al. ('108) comprises a surface layer that has incorporated therein at least one radioactive nuclide (see Figure 2(18) and column 5, lines 19-21); and a substrate and a self-assembled layer that has incorporated therein at least one radioactive nuclide (see Figure 2(16 and 18) and column 5, lines 19-21). Further, Examiner states that the layer of metallic gold [Figure 2(16)] covering a portion of a body [Figure 2(14)] of the device of Sorensen et al. ('108) is the substrate of the claimed device; and the radiation-emitting layer, which is the self-assembled layer [Figure 2(18)] of Sorensen et al. ('108) is the self-assembled layer that has incorporated therein at least one radioactive nuclide of the claimed device. Thus, the device of Sorensen et al. ('108) meets all structural limitation of claims of the present Application. Also, Applicant argues that the devices of the present invention are smaller than Sorensen, more flexible and more uniformly coated with the self-assembling surface layer. Examiner states that limitations provided by Applicant are not claimed limitations. Thus, the rejection of claims 1, 2, 4, 5, 7, 9-13 and 16 under 35 U.S.C. 102(e) as being anticipated by Sorensen et al. ('108) is deemed proper.

4. Applicant's arguments, see pages 6-8 under "*Claim Rejection – 35 U.S.C. § 103*", filed on July 28, 2003, with respect to claims 3, 6, 8, 14 and 15 have been fully considered and are persuasive. The rejection of claims 3, 6, 8, 14 and 15 has been withdrawn.

Allowable Subject Matter

5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art, either alone or in combination, teaches or suggests a device comprising either a substrate, wherein the substrate is selected from the group consisting of stainless steel, Nitinol, silicon, quartz, cobalt chrome and polymers, or a self-assembled layer anchored by phosphonate. Also, none of the prior art, either alone or in combination, teaches or suggests a device comprising either a surface layer, wherein the surface layer is formed of a radioactive material that has been activated to induce radioactivity therein after its final formation, or having a thickness of less than 10 nm.

6. Claims 3, 6, 8, 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric F Winakur can be reached on (703) 308-3940. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Nikita R Veniaminov
Examiner
Art Unit 3736

October 06, 2003.



ERIC F. WINAKUR
PRIMARY EXAMINER